

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF OHIO  
EASTERN DIVISION

IN RE: DAVOL, INC. / C.R. BARD,  
INC. POLYPROPYLENE HERNIA  
MESH PRODUCTS LIABILITY  
LITIGATION

Case No. 2-18-md-2846

JUDGE EDMUND A. SARGUS, JR.  
Magistrate Judge Kimberly A. Jolson

This document relates to:  
ALL ACTIONS.

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PLAINTIFFS' STEERING COMMITTEE'S MEMORANDUM IN OPPOSITION TO  
DEFENDANTS' REQUEST FOR EITHER A *LONE PINE* ORDER OR A DOCKET  
CONTROL ORDER

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The PSC submits this response and opposition to Defendants C.R. Bard, Inc. and Davol Inc.'s Motion for a Docket Control Order [ECF No. 627]. The PSC received Defendants' unannounced and unanticipated motion<sup>1</sup> on Friday afternoon before Memorial Day weekend; the timing of which is not lost on the PSC.

As set forth in more detail below, Defendants' motion fails on multiple levels, including wholly ignoring a prior holding by this Court on a nearly identical proposal in a prior MDL the Court presided over, as well as the body of case law (set forth below) that has rejected *Lone Pine* or Docket Control Orders at this phase of a litigation. Defendants' motion should be denied in its entirety.<sup>2</sup>

Moreover, the Court should consider the imposition of costs for the opposition of this motion and/or some other deterrent to prevent frivolous filings like this; which based upon the law, the underlying facts, and history of this litigation, is unequivocally meritless, if not harassment of plaintiffs who are rightly before this Court.

## **I. INTRODUCTION**

On August 6, 2018, the Judicial Panel on Multidistrict Litigation ("JPML") entered an Order consolidating the cases filed against Defendants C.R. Bard, Inc. and Davol, Inc. (hereinafter collectively "Bard" or "Defendants") by plaintiffs who claimed injury as a result of the implantation of their defective hernia mesh products. In doing so, the Panel found that these actions shared common questions of fact arising out of allegations related to Defendants' hernia mesh products that "can lead to complications when implanted in patients, including adhesions, damage

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<sup>1</sup> Not only did Defendants fail to meet and confer on this entire issue, they also failed to send the PSC their proposed Case Management Order for review and comment prior to filing their motion, which has been the parties' routine practice since this MDL's inception.

<sup>2</sup> The PSC is appreciative that this matter has been placed on an expedited briefing track so as to dispose of the meritless relief sought without delay and any further distraction.

to organs, inflammatory and allergic responses, foreign body rejection, migration of the mesh, and infections.” *See* August 6, 2018 Transfer Order from JMPL (Dkt. No. 1) (“Transfer Order”).

Despite the fact that this MDL was formed to include injuries that did not include the removal of their hernia mesh product, including adhesions, damage to organs, infections, or inflammatory and allergic responses, Defendants now seek to unilaterally reduce the scope of this MDL through the entry of a Docket Control Order, more commonly known as a *Lone Pine* order, to those cases where there is an undefined and ever-changing “compensable injury.”

Defendants’ premature and overly burdensome docket control motion is nothing more than an attempt to circumvent the Federal Rules of Procedure and obtain *de facto* summary judgment without the burden of satisfying the requirements of Fed. R. Civ. P. 56. Defendants’ motion therefore should be denied because this litigation does not present one of those “exceptional cases” where the procedural devices at the disposal of the parties by statute and federal rule have either been exhausted or have not been able to accommodate the unique issues of this litigation. *See McManaway v. KBR, Inc.*, 265 F.R.D. 384, 388 (S.D. In. 2009); *In re Digitek Prod. Liab. Litig.*, 264 F.R.D. 249, 259 (S.D.W.V. 2010).

Of further note, Defendants’ brief is replete with nonsensical and unsupported statements, including claims such as:

- “Despite the maturity of this litigation, Plaintiffs continue to file cases at a high rate”

Response: Of course cases will continue to be filed. The harm and damage caused by Defendants’ defective products are often times only discovered years later because of the latent nature of the injuries and product failures. *See, e.g., Milanesi et al v. C.R. Bard, Inc., et al.* – 2:18-cv-01320-EAS-KAJ. Further, most of Defendants’ defective products are still on the market, being implanted—and ultimately injuring—patients every day.

- The newer cases are, on average, weaker than the body of cases that were pending in 2018 and early 2019...”

Response: This statement is at best wholly subjective, and incorrect. Moreover, the fact that cases are “weaker” or “stronger” based upon a date of diagnosis and date of filing (given statute of limitations that often provide 3, 4, 5, and even 6 years to file a lawsuit after discovery of an injury) is simply a misguided statement.

These baseless statements appear in the very first paragraph of Defendants’ motion and are just two examples of a myriad of conclusory and misguided statements asserted by Defendants.

Defendants also allude to the settlement posture of this litigation. Many of the comments peppered throughout their motion border on, and arguably, violate Federal Rule of Evidence 408, including what constitutes a “compensable injury”. *See, e.g.*, Def. Mot. at 7 “[r]equiring proof from an apparent PiP case of a medical diagnosis of compensable injury will be an effective way to determine which cases do not merit further time or effort from the parties or Court.” The PSC will not respond to intimations about settlement, its posture, or rebut claims regarding same. Two wrongs do not make a right. However, suffice to say, there have been significant discussions about certain of these issues in Defendants’ brief, including around alleged Product-in-Place (“PiP”) cases, of which the Court and its Special Master are aware.

## **II. ARGUMENT**

### **A. *Lone Pine History and Background***

Defendants’ request for entry of a *Lone Pine* order derives from an unreported New Jersey environmental toxic tort case, *Lore v. Lone Pine Corp.*, 1986 N.J. Super. LEXIS 1626 (N.J. Super. Nov. 18, 1986). In *Lone Pine*, plaintiffs initiated suit against 464 defendants claiming that their properties had been depreciated in value because of polluted waters arising from the Lone Pine landfill. *Id.* at \*2. As noted by the *Lone Pine* court, “defense counsel required sufficient information to provide defenses and to determine which of the multiple defendants might have been involved in the alleged dumping of certain chemicals.” *Id.* at \*4-5. However, the court determined that, “upon the face of the Complaint, no *prima facie* claim for personal injuries or

property damage appear[ed],” *id.* at \*1, and “plaintiffs’ counsel [] failed to provide anything that resembles a *prima facie* cause of action based upon property diminution or personal injury.” *Id.* at \*7. See also *McManaway*, 265 F.R.D. at 386.<sup>3</sup> It was for this reason the court entered an order (now referred to as “*Lone Pine*” orders) requiring plaintiffs to provide documentation with respect to each claim for personal injuries.

“*Lone Pine* orders are ‘pre-discovery’ orders designed to handle the complex issues and potential burdens on defendants and the courts in mass tort litigation by requiring plaintiffs to produce some evidence to support a credible claim.” *Abrams v. Ciba Specialty Chems. Corp.*, 2008 U.S. Dist. LEXIS 86487, \*19 (S.D. Ala. Oct. 23, 2008). *See also In re Digitek*, 264 F.R.D. at 255 (“A *Lone Pine* order is designed to assist in the management of complex issues and potential burdens on defendants and the court in mass tort litigation, essentially requiring plaintiffs to produce a measure of evidence to support their claims at the outset.”); *McManaway*, 265 F.R.D. at 385 (“In most of the *Lone Pine* cases we have reviewed in coming to this conclusion, the *Lone Pine* order was issued only after one party was refusing to comply with discovery requests or when the plaintiffs failed to set forth a *prima facie* claim.” quoting *Simeone v. Girard City Bd. of Educ.*, 872 N.E. 2d 344, 352 (Oh. Ct. App. 2007)).

Indeed, this Court is no stranger to a party in a complex multidistrict litigation seeking invocation of a *Lone Pine* order. In a prior personal injury MDL, this Court refused to adopt the request to implement a *Lone Pine* order. As is typically the case when courts hear a request for a *Lone Pine* order, the phase of the litigation was post-settlement, and, notwithstanding the post-settlement posture of the litigation, this Court still declined to utilize *Lone Pine*, holding that a

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<sup>3</sup> In addition, the Environmental Protection Agency had issued a Record of Decision (“R.O.D.”) that was a summary of sixteen studies on the *Lone Pine* Landfill. The R.O.D. cataloged and evaluated all the information available on the *Lone Pine* problem and the location of the resulting pollution and had concluded that there was no problem with ground water contamination. *See Lone Pine*, 1986 N.J. Super. LEXIS 1626 at \*3, \*6.

*Lone Pine* order is inappropriate when there is “no reason to believe that spurious or meritless cases are lurking in...the docket.” *In Re: Du Pont De Nemours and Company, C-8 Personal Injury Litigation* (Civil Action No. 2:13-md-2433), Case Management Order No. 24, ECF No. 5140, dated June 22, 2018.<sup>4</sup> Defendants’ unsupported claims in this regard add nothing to support “spurious or meritless cases are lurking in...the docket.”

**B. Use of a *Lone Pine* Order is Not Necessary and Inappropriate for this Litigation at this Time**

Since the *Lone Pine* decision, courts have at times (and rarely, at that) used *Lone Pine* orders as case management tools to require basic information about a plaintiff’s claims where such information is lacking. “*Lone Pine* orders may not be appropriate in every case, and even when appropriate, they may not be suitable at every stage of the litigation.” *McManaway*, 265 F.R.D. at 365 quoting *In re Vioxx*, 557 F. Supp. 2d at 744. In evaluating requests for *Lone Pine* or modified case management orders, courts have found that a number of factors may be relevant, including (1) the posture of the litigation; (2) the case management needs presented, (3) external agency decisions that may bear on the case; (4) the availability of other procedures that have been specifically provided for by rule or statute; and (5) the type of injury alleged and its cause. *Roth v. Cabot Oil & Gas Corp.*, 287 F.R.D. 293, 297 (M.D. Pa. 2012), citing *In re Digitek* at 256 (considering these factors, and denying motion for *Lone Pine* order in multi-district litigation brought by thousands of plaintiffs against defendants who manufactured and distributed heart medication)). As set forth below, an exploration of each of these factors—factors that were ignored by Defendants in their motion—compel denial of Defendants’ extraordinary request.

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<sup>4</sup> In the DuPont MDL, like here, the request for *Lone Pine* was out-of-the-blue. However, at least there the request followed a global settlement. Here, the litigation is still in the bellwether process.

It is also well-settled that *Lone Pine* Orders create unfair conditions precedent to lawsuits. Moreover, in the context of its prior *Lone Pine* decision in the DuPont MDL, this Court held that “there [was] simply no need for this Court to enter the extraordinary *Lone Pine* order in an attempt to weed out frivolous or otherwise non-viable claims as early as possible” and an “entry of a *Lone Pine* order under the circumstances here amounts to an unprecedented condition precedent to filing a claim and insertion of defense counsel screening of a plaintiff’s claims.” *In Re: Du Pont*. Indeed, this Court found that there was “simply no justification for such conditions, none of which is required by the Federal Rules of Civil Procedure or this Court’s Local Rules.” *Id.* The same logic applies here.

Lastly, the body of cases Defendants rely on in support of *Lone Pine* are all distinguishable from the current posture of this case since, when it has been used, *Lone Pine* was either used as part of a settlement process (and as a post-settlement tool) or used to identify signature injuries. And, in another instance, Defendants simply misstate that *Lone Pine* was even applied.

As noted above, Courts have found that a number of factors may be relevant in considering requests for *Lone Pine*. As explored in detail below, none of the factors weigh in favor of granting a *Lone Pine* request here.

### **1. The Current Posture of the Litigation Does Not Warrant Lone Pine**

“Resorting to crafting and applying a Lone Pine order should only occur where existing procedural devices explicitly at the disposal of the parties by statute and federal rule had been exhausted or where they could not accommodate the unique issues of this litigation.” *In re Digitek*, 264 F.R.D. at 259. This litigation has been pending for just over three-and-a-half years and, as recognized by Defendants, “the MDL has moved at a fast pace, with extensive generic fact and expert discovery and verdicts in two bellwether trials.” See Defs. Mot. at 18. However, given that

there are still bellwether trials scheduled and only two of the twenty-four products at issue in this MDL have been the subject of those bellwether trials, there are still a multitude of unique issues left to litigate. In their motion, Defendants refer to PiP cases as being potentially non-compensable; as noted above, the scope of what is and what is not compensable, is a topic related to settlement and one the PSC is not prepared to address in potential violation of FRE 408.

As it relates to individual cases in this MDL, each Plaintiff is required to serve a completed Plaintiff Profile Form (“PPF”)<sup>5</sup>, provide medical authorizations for the release of medical records, and produce copies of any documents in their possession. *See CMO 8.* In those cases where a Plaintiff did not comply with the discovery mandates, Defendants can (and do) seek dismissal. This mechanism serves to eliminate any Plaintiff who does not wish to actively litigate their claims.<sup>6</sup>

To date, the procedural devices implemented by the Court have worked well and the parties should not deviate.

## **2. There Are No Peculiar Case Management Needs Presented by This Litigation**

Defendants are unable to articulate any peculiar case management needs presented by this litigation that this Court is unable to handle or that require implementation of *Lone Pine* in the form proposed by Defendants or any docket control order.

To the contrary, the litigation, its case management, and the cases before this Court have proceeded in a manner that has become commonplace for medical device and other personal injury

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<sup>5</sup> This discovery device has the same effect as Interrogatories and Document Requests under the federal rules.

<sup>6</sup> The flip side to this, is that each of the thousands of plaintiffs in this MDL with “compensable cases” are not permitted to serve discovery on Defendants or jump the Court’s bellwether process to get a trial. These processes of managing discovery and the orderly management of a large MDL are all sanctioned by the Manual on Complex Litigation and used to foster the overall case management of MDLs. See Manual for Complex Litigation (Fourth) §11 (2004). Accordingly, nothing Defendants suggest warrant deviation from the management of this MDL as the Court has set forth in this case and as it did in its prior MDL.

MDLs. The tools implemented by the Court and the parties have enabled Plaintiffs to put Defendants on notice of claims being alleged and have enabled each Plaintiff to provide Defendants with detailed information related to specific injuries by virtue of a short form complaint. *See* CMO 9. Further Defendants are, permitted to either adopt and incorporate the responses set forth in Defendants' Master Answer or assert new ones for each Complaint filed and served. For cases selected into the Bellwether Process, Defendants would have the opportunity to "interpose more robust and detailed Answers." *See, e.g.* CMO 9.

To the extent these Defendants are displeased that more cases are being filed, that is purely a result of the defective nature of the product, the successful and overwhelming liability story developed by the PSC, and likely other factors.<sup>7</sup>

### **3. The Availability of Other Procedures That Have Been Specifically Provided for By Rule Or Statute Make *Lone Pine* Inappropriate**

An important criticism regarding the use of a *Lone Pine* order is that "it gives courts the means to ignore existing procedural rules and safeguards." *Roth*, 287 F.R.D. at 298, citing *Simeone v. Girard City Bd. of Educ.*, 171 Ohio App. 3d 633, 872 N.E.2d 344, 350 (Ohio Ct. App. 2007). Defendants' request for a *Lone Pine* order requiring Plaintiffs to produce the equivalent of an expert report in the form of an "affidavit from a qualified, licensed surgeon attesting that he or she opines to a reasonable degree of medical certainty that a causal connection exists between the plaintiff's alleged symptomatic injuries and the Bard hernia device in question" or face dismissal

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<sup>7</sup> There is no secret that these Defendants settled a small number of cases in the Rhode Island state court litigation approximately one year ago; and doing so is certainly Defendants' prerogative. It is generally accepted in negotiating any mass tort matters that there typically is an influx of cases following the announcements of settlements occurring. It is for this reason that settlements are typically, in large cases, orchestrated via global settlement or if not, a plan to systematically address all cases and/or inventories of cases and manage the influx of new cases is addressed. However, the Defendants here, likely with able counsel, did not engage in this process; and should have been aware that settling a small percentage of cases in one venue with no cognizable plan to resolve the large majority in any other venues would likely increase awareness of the ability for injured plaintiffs to get compensation, and in-turn lead to more lawsuits (many of which are still not filed at Defendants' repeated requests).

of their case is an unnecessary and uncalled for burden as well as an end-run around summary judgment requirements. Bard’s attempt to move for summary judgment *en masse* without due process and without the crucial safeguards of Rule 56 must fail. *See* Nora Freeman Engstrom, *The Lessons of Lone Pine*, 129 Yale L.J. 2, 43 (2019) (“[T]he worry is that, by using a homemade mechanism (*i.e.*, a *Lone Pine* order) to extinguish plaintiffs’ well-pleaded complaint, a trial court may deprive plaintiffs of crucial safeguards that Rule 56 would otherwise furnish.”)

In *Digitek*, the court elected to rely upon the procedural tools expressly provided for under the Federal Rules of Civil Procedure rather than to rely upon the court’s own inherent case management authority to fashion a case management order that required the plaintiffs to produce evidence or otherwise face dismissal. *Id.* at 259. The court wrote: “I believe it more prudent to yield to the consistency and safeguards of the mandated rules [providing for dispositive motions and sanctions] especially at this stage of this litigation. Claims of efficiency, elimination of frivolous claims and fairness are effectively being addressed using the existing and standard means.” *Id.* Here, just as in *Digitek*, this Court should “yield to the consistency and safeguards” of the Rules, as well as the Court’s own flexibility and discretion to address disputes as they arise, as opposed to entering the proposed *Lone Pine* order. Again, Defendants remain free to pursue dispositive motions if warranted, after appropriate discovery has been conducted, if they believe that Plaintiffs have not developed evidence to support their claims. Much like the *Digitek* Court observed:

Resorting to and crafting a *Lone Pine* order should only occur where existing procedural devices explicitly at the disposal of the parties by statute and federal rule have been exhausted or where they cannot accommodate the unique issues of this litigation. We have not reached that point. 264 F.R.D. at 259.

Expressing similar concerns, another court maintained that *Lone Pine* orders can be useful devices but that they should not be a “substitute for … a motion for summary judgment.” *McManaway v. KBR, Inc.*, 265 F.R.D. 384 (S.D. Ind. 2009). “A *Lone Pine* order should issue only in an exceptional case and after the defendant has made a showing of significant evidence calling into question the plaintiffs’ ability to bring forward necessary … causation and other scientific information.” *McManaway*, 265 F.R.D. at 389. Indeed, “[r]esorting to and crafting a *Lone Pine* order should only occur where existing procedural devices explicitly at the disposal of the parties by statute and federal rule have been exhausted or where they cannot accommodate the unique issues of this litigation.” *Roth*, 287 F.R.D. at 300. This case does not yet present such a situation.

In short, Defendants’ request that the Court require Plaintiffs to prove causation beyond the standard defined in the Rules is inappropriate and should be denied. *See Adinolfe v. United Techs. Corp.*, 768 F.3d 1161, 1168 (11th Cir. 2014) (*Lone Pine* orders “should not be used as (or become) the platforms for pseudo-summary judgment motions at a time when the case is not at issue and the parties have not engaged in reciprocal discovery.”)

#### **4. The Type of Injury Alleged and its Cause Do Not Warrant *Lone Pine* Here**

Plaintiffs do not present with signature injuries or any injury that requires a specific test to diagnose. *Lone Pine* orders were utilized in three litigations to target specific injuries; and of note in two of them they were after the bellwether process and into settlement phases. *See e.g. In re Zostavax (Zoster Vaccine Live) Prods. Liab. Litig.*, MDL No. 2848, No. 18-md-2848, 2022 U.S. Dist. LEXIS 57935, at \*2-3 (E.D.Pa March 30, 2022) (A *Lone Pine* order was appropriate where “there is compelling medical authority that a laboratory test of the shingles rash of a person who

has had chicken pox is the only way to tell whether the shingles was caused by the virus strain contained in Zostavax or the wild-virus strain from chicken pox latent in a person's body.”).

Nor are the parties in a settlement posture such that certain injuries are lacking scientific or medical support through an adverse Daubert decision. *See In re Fosamax Prods. Liab. Litig.*, No. 06 MD 1789 (JFK), 2012 U.S. Dist. LEXIS 166734, at \*8-9 (S.D.N.Y Nov. 20, 2012) (limiting the *Lone Pine* order to cases where osteonecrosis of the jaw or osteomyelitis were not alleged); and *In re Yasmine and Yaz (Drospirenone) Mktg, Sales Practice and Prods. Liab. Litig.*, MDL No. 2100, No. 09-md-2100 (S.D. Ill. Aug. 3, 2015) (applying a *Lone Pine* order to remaining cases not subject to the negotiation provisions set forth for plaintiffs suffering from a venous thromboembolism or eligible for the arterial thromboembolism settlement program). Further, the Fosamax decision applied the *Lone Pine* decision to cases outside the claimed injury focus of that MDL for which the common benefit expert work-up had been completed and no such instance applies in this MDL.

**C. The *Lone Pine* Orders Proposed by Defendants are Not Efficient and Will Not Advance the Litigation**

Defendants seek two *Lone Pine* orders—one for specific causation and another that seeks a certification by plaintiffs' counsel as to four factors.

**1. The Proposed *Lone Pine* Order Seeking an Expert Report of all Alleged Injuries Asserted by a Plaintiff is Not Efficient, Not Warranted, and Will Not Advance the Litigation**

Defendants ask this Court to enter a *Lone Pine* order requiring “plaintiffs to produce proof of a medical diagnosis of compensable injury in order to proceed,” which “could include an affidavit from a qualified, licensed surgeon attesting that he or she opines to a reasonable degree of medical certainty that a causal connection exists between the plaintiff's alleged symptomatic injuries and the Bard hernia device in question.” *See* Defs. Mot. at 6. At this stage of this litigation,

Defendants' request is inefficient, unduly burdensome, and is Defendants' attempt to circumvent Fed. R. Civ. P. 56. "When the *Lone Pine* order cuts off or severely limits the litigant's right to discovery, the order closely resembles summary judgment, albeit without the safeguards that the Civil Rules of Procedure supply." *McManaway*, 265 F.R.D. 384, 365 (S.D. In. 2009) quoting *Simeone*, 872 N.E. 2d at 350.

Defendants' request, at this juncture of the litigation is not only unduly burdensome, and a poor attempt to circumvent judicial safeguards provided by Fed. R. Civ. P. 56, it is also is premature. Indeed the very phrasing of Defendants' ask suggests a post-settlement posture as Defendants seek this Court to force plaintiffs to provide medical evidence of a "compensable injury," but there has been no definition or negotiation of just what a "compensable injury" entails.<sup>8</sup>

In Defendants' attempt to sway the Court's opinion away from its prior holdings (*see, e.g.*, *In Re: Du Pont De Nemours and Company, C-8 Pers. Injury Litig.* (Civil Action No. 2:13-md-2433), Case Mgmt. Order No. 24, ECF No. 5140), they cite to a multitude of cases, which are inapplicable here; and most cited by the Defendants in that prior MDL. The vast majority of the cases that Defendants cite to had *Lone Pine* orders entered after the case entered into settlement proceedings.

- *In re Vioxx Prods. Liab. Litig.*, MDL NO. 1657, 557 F. Supp. 2d 741 (E.D. La. 2008) – *Lone Pine* orders were entered following the massive global settlement of approximately 27,000 claims. These *Lone Pine* orders were issued to assist in the administration of the settlement and to address post-settlement cases.
- *In re Avandia Mktg, Sales Practices & Prods. Liab. Litig.*, MDL No. 1871, 2010 WL 4720335 (E.D. Pa. Nov. 15, 2010) – *Lone Pine* orders were entered into the MDL after defendants had already entered into settlement

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<sup>8</sup> As this Court is aware having tried two Bellwether cases in this MDL (and denying summary judgment in both cases), Defendants' litigation team would have this Court (and any jury) believe that not a single case filed in this MDL should be compensated.

agreements with individual firms or groups of firms to resolve their inventories. The court also appointed a Special Master dedicated to mediation and resolution of settlement related issues a mere week after the entry of the *Lone Pine* order and placed cases on mediation tracks in an effort to wind down the MDL.

- *In re Testosterone Replacement Therapy (“TRT”) Products Liability Litigation*, MDL No. 2545, Master Docket Case No. 1:14-cv-01748, 2018 U.S. Dist. LEXIS 205125 (N.D. Ill. June 11, 2018) - The Defendants reliance on the *TRT* decision and portrayal of the facts is misleading and disingenuous. Defendants state that “*TRT* had over 7700 cases when it issued its order” (see Defs. Memo at 17), but Defendants neglect to explain that the *Lone Pine* order in *TRT* only applied following a settlement. And more specifically, only to cases involving the two of the four defendants who settled their cases. The 7700 pending cases that Defendants cite to actually encompass cases with all defendants, both settled and unsettled. Therefore, the *Lone Pine* order in *TRT* only applied to a subset of the 7700 cases, consisting of cases with the settled defendants.<sup>9</sup>
- *In re Xarelto (Rivaroxaban) Prods. Liab. Litig.*, MDL No. 2592, 2:19-cv-14669, 2021 U.S. Dist. LEXIS 25296 (E.D. La. Feb. 10, 2021) – Like Vioxx, *Lone Pine* orders were entered following the massive global settlement of close to over 25,000 claims. These *Lone Pine* Orders were issued to assist in the administration of the settlement and to address post-settlement cases.
- *In re Ethicon Physiomesh Flexible Composite Hernia Mesh Prods. Liab. Litig.*, Civil Action No. 1:17-MD-02782-RWS, Practice and Procedure Order No. 26, ECF No. 743 (N.D. Ga. May 13, 2021) and *In re Physiomesh Mesh Litig.*, Master Case No. ATL-L-2122-18, Case Management Order No. 20 (N.J. Sup. Ct. L. Div. Atlantic Cty. May 13, 2021) – Although no settlement agreement had been officially announced when the *Lone Pine* order was entered on May 13, 2021, entry of the *Lone Pine* order was contingent upon resolution involving cases filed prior to May 13, 2021 (the date of the *Lone Pine* order). Moreover, within days of the *Lone Pine* order, the first bellwether trial was stayed and all deadlines related to Trial Pool Cases were suspended indefinitely. There is no question the *Lone Pine* order was meant to apply to post-resolution cases only.<sup>10</sup>

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<sup>9</sup> Michael London served as Chairperson of the Plaintiffs’ Executive Committee in the *TRT* MDL alongside Mr. Grand’s partner, Chris Seeger who was co-lead counsel.

<sup>10</sup> The undersigned co-lead Counsel Kelsey Stokes can attest to these facts.

Importantly, in each of these cases the settlement was achieved, and *Lone Pine* orders were issued to assist in the settlement administration and winding down of the litigation for unsettled cases.

In the other cases that Defendants rely on to support their *Lone Pine* request, the circumstances are widely different than the circumstances of the instant case and the *Lone Pine* orders were extremely case specific or not even *Lone Pine* orders.

For example, the circumstances of the instant case vary greatly from the recent decision in *In re Zostavax (Zoster Vaccine Live) Prods. Liab. Litig.*. There, the court entered a *Lone Pine* order following summary judgment and Daubert in bellwether cases after there was evidentiary showing and finding that there was a specific medical test that could be performed to conclusively prove causation. Specifically, the Court found that the only evidence that could be used to establish the injury was such a blood test. The facts of that tiny MDL are very different than here; specifically, because no such test exists and Defendants have not defined what constitutes a “compensable injury.”

As it might pertain to PiP cases, the PSC submits an ample mechanism and agreement has been set forth. Defendants state “it appears that a significant percentage of the pending cases are cases where the only device at issue is still implanted, that is product in place” cases (“PiP”). *See* Def Mot. at p. 7 This is simply not true. The PSC and Defendants engaged in a review of 6,000 cases randomly chosen. Review of the medical records revealed that approximately 400 of these approximately 6,000 cases were within an agreeable definition of PiP. Thus less than 7%, hardly “a significant percentage”, were PiP cases.<sup>11</sup>

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<sup>11</sup> It should be noted that just because a product has not been removed does not mean that the case is not meritorious as there are many reasons why a product that has caused significant injury to a patient is still in the patient’s body (e.g., too dangerous to remove, etc.).

Defendants also rely on *In re Zimmer Nexgen Knee Implant Products Liab. Litig.*, MDL NO. 2272, Master Docket Case No. 1:11-cv-05468, 2016 WL 3281032 (N.D. Ill. June 10, 2016). *See* Defs. Memo at 5. There, a *Lone Pine* order was entered only with regard to plaintiffs who were pursuing specific claims related to femoral loosening resulting from high flexion activities, loosening of a tibial component other than an MIS 5950 tibial component or loosening resulting from high flexion activities of an MIS tibial component which was implanted with a drop down stem. This was a specific subset of injuries and cases filed in that MDL and entered in addition to CMO No. 9 to “encourage continued progress toward resolution.” Once again completely distinguishable from the facts and posture here.

Defendants also rely on *In re 3M Combat Arms Earplug Prods. Liab. Litig.*, MDL No. 2885. They specifically site to a docket control order that was issued requiring plaintiffs “to submit a specific form or report by the deadline established.” *See* Defs. Mot. at 5, citing to *In re 3M Combat Arms Earplug Prods. Liab. Litig.*, MDL No. 2885, May 6, 2022. This gross oversimplification is very misleading and frankly not accurate. What the 3M Court did was require the submission of a form confirming the military service of a plaintiff. Thus, 3M Court did exactly what this Court had previously done by requiring a Plaintiff Profile Form.<sup>12</sup> In the present case, there is already a procedure in place for plaintiffs to submit a Plaintiff Profile Form. As such, the decision in the *3M Combat Arms Earplug* litigation has no bearing or applicability here.

Defendants also rely on *In re Fosamax Prods. Liab. Litig.*, No. 06 MD 1789 (JFK), 2012 U.S. Dist. LEXIS 166734, (S.D.N.Y Nov. 20, 2012) as a specific example of a litigation that imposed a *Lone Pine* order prior to a settlement.<sup>13</sup> *See* Def. Mot. at 16. However, what Defendants

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<sup>12</sup> Of note, co-lead counsel, Tim O’Brien’s partner is currently liaison counsel in that MDL and PEC member Jeff Grand’s partner, Chris Seeger is co-lead counsel of that MDL.

<sup>13</sup> Of note, co-lead counsel, Tim O’Brien was lead counsel in the Fosamax MDL.

neglect to mention is that Merck made two prior motions for *Lone Pine* orders that were denied as premature. On Merck's third request for a *Lone Pine* order, they sought to apply the order to all plaintiffs, as Defendants do in this matter, despite previously acknowledging that osteonecrosis of the jaw and osteomyelitis claims had validity. The court found that “In crafting a *Lone Pine* order, a court should strive to strike a balance between efficiency and equity,’ (quoting *Vioxx*, 557 F. Supp, 2d 741, 744 (E.D.La. 2008). While a *Lone Pine* order would certainly advance efficiency within this MDL, limiting the scope of the order will effectively safeguard plaintiffs' rights.” *Id* at 8. This balance was of the utmost importance to the *Fosamax* and *Vioxx* courts, although not at all considered by Defendants in their motion.<sup>14</sup>

Defendants also rely on the Cook IVC MDL. Defendants argue, the “*Cook IVC* had about 8200 pending cases when it issued its second order.” *See* Defs. Memo at 17, referring to *In re Cook Med., Inc., IVC Filters Mkt'g, Sales Pract. & Prod. Liab. Litig.*, MDL No. 2570, Mar. 29, 2022. However, Defendants neglect to mention that this order only required medical records to be provided. As noted above, there is already a procedure in place for the production of medical records, in that medical records are produced contemporaneously with the PPF, as well as duly executed authorizations so that Defendants can obtain any additional medical records they desire. *See, e.g.*, CMO 9.

As shown above, the cases relied upon by Defendants either permitted a *Lone Pine* order with regards to settlement administration or implementation of *Lone Pine* was for very unique case-specific facts not present here.

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<sup>14</sup> Indeed, this truly underscores that the times where *Lone Pine* orders are utilized – the overwhelming majority of which are in settlements – it is to single out “non-compensable injury cases.” Ergo, Defendants have unwittingly underscored in their own advocacy why a *Lone Pine* order's issuance at this time is not warranted or ripe.

**2. Defendants Second *Lone Pine* Request that Certifications be Provided from Plaintiffs' Counsel is Burdensome, Not Necessary, and Unprecedented.**

In seeking multiple *Lone Pine* orders, Defendants ask this Court to impose upon plaintiffs' counsel the requirement to submit certifications that plaintiff counsel believes in good faith that: (1) the plaintiff is pursuing a claim of a compensable injury caused by Defendants' product; (2) another lawsuit was not filed with the same claims asserted here; (3) the claims are not barred by the statute of limitations or statute of repose; and (4) the claims were not resolved in another litigation or were the subject to a prior dismissal with prejudice. *See* Defs. Mot. at 10.

These four prongs are each addressed below.

**a. The Proposed Requirement that Plaintiff Counsel Certify That a Plaintiff is Pursuing a Compensable Injury is Both Unprecedented, Unnecessary, and Contrary to Applicable Law**

As discussed in greater detail above, Defendants neglected to define what a "compensable injury" entails. A *Lone Pine* order to this effect is inappropriate at this juncture of the litigation.

Defendants state "any plaintiff who claims to have a compensable injury—implicit in bringing a products liability suit in the first place—should also be prepared to provide proof of a medical diagnosis of a compensable injury." *See* Def brief at p 8. As noted above, this uses the flawed premise of what a "compensable injury" is. Secondly, this statement ignores the fact that CMO 9 already requires plaintiffs to serve a PPF, provide any medical records he/she has, as well as execute and provide duly executed authorization for the release of all of their relevant medical records. Thus, the very information that is required under the process of discovery and the Federal Rules that govern that exchange of information is already set forth in this MDL.

Moreover, in the initial Kugel MDL (MDL-1842), Defendants did in fact resolve through settlements, cases that had PiP and were wholly asymptomatic with no manifestation of any

cognizable injury. Again, as noted above, the PSC will refrain from discussing settlements or settlement discussion related to this MDL.

**b. The Proposed Requirement that Plaintiff Counsel Certify That another Lawsuit was not filed (e.g. Dual Representation Cases) is Unprecedented, Unnecessary and Can be Addressed Otherwise**

Defendants' request for a counsel certification certifying that there are no dual representation cases pending in the active MDL docket is inappropriate, unnecessary, and unduly burdensome. In this litigation, there is already a procedure in place to remove cases with dual representation from the docket. When Defendants believe there is a duplicate filed claim, Defendants simply contact Plaintiff's counsel notifying them of the potential duplicate filing and request that the case be voluntarily dismissed. The plaintiff attorneys then communicate with each other, determining if in fact it is a dual represented client, and then one of the attorneys dismisses his/her filed case, leaving only one active case on the docket. Importantly, when looking at the docket, it is not always readily apparent whether a case has dual representation and requiring plaintiffs' attorneys to research thousands of cases when there is already a procedure in place with defendants reach out directly to plaintiffs' counsel regarding suspected dual represented cases is extremely burdensome. As is evidenced by the current procedure, the issue of dual represented cases can be resolved in a manner that is less burdensome to the plaintiffs and the Court, in a way that will not stall the discovery process and settlement negotiations.

For Defendants to contend that Plaintiffs want to crowd the docket with duplicate cases is absurd. No plaintiff attorney intends to file (and incur the cost of a non-refundable filing fee) a duplicate case where his/her client may be represented by another attorney nor will the PSC countenance dual represented cases being maintained on the docket once identified. While duplicate filings do unfortunately occur, they are issues that occur in every mass tort/MDL and

easily rectified and removed from the docket by counsel whenever notified by a Defendant. Requiring a *Lone Pine* order here is unduly burdensome on the plaintiffs and the Court and a waste of the Court's valuable resources.

Efficiently managing and addressing duplicative filed cases and/or dual represented plaintiffs can be easily worked out by the parties. Moreover, these dual represented cases or dual filed cases are surely a small percentage and can be addressed and cleaned up on the docket by and between the parties' liaison counsel and/or through simple notifications from defense counsel to the impacted law firms.

**c. The Proposed Requirement that Plaintiff Counsel Certify the Claims are Not Barred by Statute of Limitations or Statute of Repose is Both Unprecedented, Not Necessary and Contrary to Applicable Law**

In their motion, Defendants also seek dismissal for those cases where they believe the Plaintiff's claims may be barred by applicable statute of limitations and/or repose if they so choose. However, statute of limitations applications are factual inquiries and cannot be asserted without a complete record, and even then, are often an issue of fact. Furthermore, Defendants completely ignore the very nuanced discovery rules that exist, in the different states. All of which underscore that a statute of limitations cannot be ascertained merely by looking at dates of surgery.

Defendants state that there are "strong reasons to suspect that a substantial number of cases ultimately will be barred by statutes of limitations or repose," but this hypothetical premise is not supported or substantiated by any concrete evidence. *See* Defs. Memo at 13. Defendants' argument for the inclusion of such a premature and burdensome request hinges on assumptions and conclusory statements. Defendants are once again trying to circumvent the judicial protections afforded under Fed. R. Civ. P. 56.

It is a well-settled principle of law that the statute of limitations is an affirmative defense which must be pleaded and proved by a defendant. *See Goldman v. Walco Tool & Eng'g Co.*, 243 Ill. App. 3d 981, 989, 614 N.E. 2d 42, 48 (1993) (citing *Ruddock v. First National Bank of Lake Forest*, 201 Ill. App. 3d 907, 918, 559 N.E. 2d 483 (1990)). The facts constituting any affirmative defense must be plainly set forth in the answer or reply to a complaint, so as to give color to the opposing party's claim and assert a new matter by which the apparent right is defeated. *Id.* (citing *Shute v. Chambers*, 142 Ill. App. 3d 948, 951-52, 492 N.E. 2d 528 (1986)). Failure to specifically plead the statute of limitations provision constitutes waiver of the defense. *Id.*

The burden lies with Defendants, not Plaintiffs, to establish when the applicable statute of limitations period expired by introducing credible evidence supporting its affirmative defense. Defendants' attempt to shift their burden of proof related to statute of limitations through implementation of a *Lone Pine* order is neither efficient nor equitable, does not advance the core issues of this litigation, and is inapposite to applicable laws. Lastly, and as noted above, statute of limitations arguments are highly specific and factual. A statute of limitations assessment and challenge is not simply a date of surgery, but rather it is an affirmative defense that carries a burden of proof. In most if not all instances, it is triggered on notice and knowledge for a plaintiff, including often times knowledge of the harm and who caused the harm. All of which is factual and warranting of discovery and depositions.

The Court, by agreement of the parties has selected bellwether cases to test legal issues, including affirmative defenses like statute of limitations. The Court should not now be tasked with wading into complicated choice of law issues, presenting different statutory standards for each case, as well as the enormous amount of factual discovery that would be required to make a statute of limitations challenge and then permit the defense.

**d. The Proposed *Lone Pine* Order for Claims Resolved in Another Litigation or Barred by Dismissal with Prejudice Is Both Unprecedented and Contrary to Applicable Law**

Defendants' request for a counsel certification certifying that there are no cases with claims that have been resolved in another litigation or barred by a dismissal with prejudice is inappropriate, unnecessary, and unduly burdensome. These cases, to the extent they allegedly exist, are discrete issues that can be resolved with less burdensome methods. Additionally, a case filed in this litigation would not have had its claims resolved in another case. There are many cases filed in this litigation where the plaintiffs are suffering from injuries caused by multiple hernia mesh products. While those plaintiffs' claims regarding injuries caused by other products may have been resolved through settlement by another defendant, the plaintiffs' claims have not been resolved here with the Bard Defendants regarding Bard's defective hernia mesh product(s). Regarding cases that may be subject to a prior dismissal with prejudice, the Defendants should have no issue filing a motion to dismiss a discrete subset of cases that they feel are barred in this litigation. Again, as with plaintiffs who may have multiple cases, requiring a *Lone Pine* order here is unduly burdensome on the plaintiffs and not necessary. It is also a waste the Court time and resources.

**III. CONCLUSION**

For the foregoing reasons Defendants' motion for entry of a Docket Control Order should be denied in its entirety and the Court should grant such other and further relief as it deems just, appropriate and warranted under the circumstances.

Dated: June 10, 2022

Respectfully submitted,

/s/ David J. Butler

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**CERTIFICATE OF SERVICE**

I hereby certify that on June 10, 2022, I electronically filed the foregoing with the Clerk of Court using the Court's CM/ECF system.

/s/ David J. Butler

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